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| 10/528,417 | 07/26/2006 | Martinus Antonius Hermanus Maria Wiggerinck | 0470-050863 | 2537 |

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| EXAMINER |
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SZMAL, BRIAN SCOTT

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| ART UNIT | PAPER NUMBER |
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3736

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12/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,417

Applicant(s)

WIEGERINCK ET AL.

Examiner

Brian Szmaj

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 20-39 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Specification

1. The abstract of the disclosure is objected to because the Abstract exceeds 150 words. Correction is required. See MPEP § 608.01(b).

Claim Objections

2. Claim 22 is objected to because of the following informalities: "said liquid" lacks antecedent basis. Appropriate correction is required.
3. Claim 23 is objected to because of the following informalities: "said pump means" lack antecedent basis. Appropriate correction is required.
4. Claim 24 is objected to because of the following informalities: "said liquid containing means" lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 20-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Regarding claims 20, 31 and 35, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 20 and 31 recite the insertion of a tubular means in a body cavity. The tubular means should be "adapted to be" inserted in a body cavity.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Ayre (3,540,432).

Ayre discloses a mucus sampling means and further discloses introducing a sampler tube into the entrance of the cavity; moving the tube in the cavity up to contact with the blind end of the cavity; expelling a flushing solution (the glycerine acts as a

flushing solution) from the sampler tube into the body cavity; taking a sample by suctioning material at the end of the sampler tube through an opening thereof; and the flushing solution is expelled from a chamber inside the tube and the sample is introduced the chamber. See Column 3, lines 7-10, 17-21, 38-45 and 65-68; and Column 4, lines 7-12 and 38-41.

11. Claims 35-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Lurie et al (7,207,951 B1).

Lurie et al disclose a means of obtaining a cell sample and further disclose introducing a sampler tube into the entrance of the cavity; moving the tube in the cavity up to contact with the blind end of the cavity; expelling a flushing solution from the sampler tube into the body cavity; taking a sample by suctioning material at the end of the sampler tube through an opening thereof; the flushing solution is expelled from a chamber inside the tube and the sample is introduced the chamber; and the flushing solution comprises a physiological saline solution. See Column 4, lines 2-11 and 63-65; Column 5, lines 44-67; and Column 6, lines 1-4.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 20-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432) in view of Suzuki et al (4,781,699).

Ayre, as discussed above, discloses a cytological sampling instrument and further discloses a tubular means for insertion into a body cavity, the tubular means has a curved distal end, a storage means connected to the tubular means and a vacuum means connected to the storage means and tubular means, the tubular means has a diameter of at least 1cm and has openings only at the curved distal end; a liquid containing means and pump means for expelling the liquid at the distal end of the device; an opening for expelling a liquid from the distal end of the device; the storage means comprise the liquid containing means; the liquid means has a volume of less than 10cc; a sealing means for sealing the openings; the liquid containing means contains a flushing solution (the glycerine solution acts as a flushing solution when expelled from the device when placed at the cervix); the flushing solution is expelled from the device and a sample is introduced in the device. See Column 3, lines 7-10, 17-21, 38-45 and 65-68; and Column 4, lines 7-12 and 38-41.

Ayre however fails to disclose sample openings that are less than 5mm in diameter; the vacuum means comprise a pump means; the vacuum means comprise a plunger-cylinder; and the tube comprises the cylinder.

Suzuki et al disclose a mucus sampling device and further disclose sample openings that are less than 5mm in diameter; the vacuum means comprise a pump means (the plunger acts as a pump); the vacuum means comprise a plunger-cylinder; and the tube comprises the cylinder. See Column 2, lines 20-23, 38-44, 64 and 65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ayre to include the use of small diameter openings as well as a different type of a vacuum source, as per the teachings of Suzuki et al, since it would provide a device that has the ability to obtain a mucus sample utilizing a vacuum source.

14. Claims 29, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432) and Suzuki et al (4,781,699) as applied to claims 20 and 31 above, and further in view of Lurie et al (7,207,951 B1).

Ayre and Suzuki et al, as discussed above, disclose a cervical mucus sampling means, but fail to disclose the vacuum means comprise a plunger in the tubular means, wherein abutment means are provides to define relative movement of the plunger and the tubular means; a biasing means for the plunger; and the flushing solution comprises physiological saline.

Lurie et al, as discussed above, disclose a means for obtaining cell samples and further disclose the vacuum means comprise a plunger in the tubular means, wherein abutment means are provides to define relative movement of the plunger and the tubular means; a biasing means for the plunger; and the flushing solution comprises physiological saline. See Column 4, lines 2-11 and 63-65; Column 5, lines 44-67; and Column 6, lines 1-4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ayre and Suzuki et al to include a means of biasing the plunger and utilizing saline as the flush solution, as per the

teachings of Lurie et al, since it is well known in the art to utilize a biasing means on the plunger as well as utilizing saline as a flush solution during a medical procedure.

15. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432) and Suzuki et al (4,781,699) as applied to claims 20 and 31 above, and further in view of Oster (3,815,580).

Ayre and Suzuki et al, as discussed above, disclose a means of obtaining a mucus sample, but fail to disclose a kit comprising a closable container for containing the sample, and the container is separate from the sampler.

Oster discloses a means of preserving cytological samples and further discloses a kit comprising a closable container for containing the sample, and the container is separate from the sampler. See Figures 1 and 8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ayre and Suzuki et al to include a kit with a closable container for containing the sample, as per the teachings of Oster, since it is well known in the art to obtain a cell sample and place the sample within a fixative for shipping to a lab.

16. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432) as applied to claim 35 above, and further in view of Lurie et al (7,207,951 B1).

Ayre, as discussed above, disclose a means of obtaining a mucus sample, but fail to disclose the use of a flush solution containing saline.

Lurie et al, as discussed above, disclose a means of obtaining a cell sample, and further disclose the use of a flush solution containing saline. See Column 4, lines 63-65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ayre to include the use of saline as a flush solution, as per the teachings of Lurie et al, since it is well known in the art to utilize saline as a flush solution to obtain a cell sample.

17. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432) as applied to claim 35 above, and further in view of Oster (3,815,580).

Ayre, as discussed above, disclose a means of obtaining a mucus sample, but fails to disclose providing a container for transferring the contents of the sampling tube into the container for shipping; and the container is provided with a preserving agent.

Oster, as discussed above, disclose a means of preserving cell samples and further discloses providing a container for transferring the contents of the sampling tube into the container for shipping; and the container is provided with a preserving agent. See Figures 1 and 8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ayre to include the use of a separate container for containing and preserving the obtained sample, as per the teachings of Oster, since it would provide a means of shipping the obtained sample to a lab for processing.

18. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lurie et al (7,207,951 B1) as applied to claim 35 above, and further in view of Oster (3,815,580).

Lurie et al, as discussed above, disclose a means of obtaining a cell sample, but fails to disclose providing a container for transferring the contents of the sampling tube into the container for shipping; and the container is provided with a preserving agent.

Oster, as discussed above, disclose a means of preserving cell samples and further discloses providing a container for transferring the contents of the sampling tube into the container for shipping; and the container is provided with a preserving agent. See Figures 1 and 8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Lurie et al to include the use of a separate container for containing and preserving the obtained sample, as per the teachings of Oster, since it would provide a means of shipping the obtained sample to a lab for processing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who's telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Brian Szmaj
AU 3736